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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,579	12/18/2001	Carl Johan Friddle	LEX-0274-USA	2417

24231 7590 06/28/2004

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,579	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/02, 4/1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (Claims 2-4, in part) in the reply filed on 4/26/04 is acknowledged.

Inventorship

2. In view of the papers filed 4/26/04, the inventorship in this nonprovisional application has been changed by the deletion of Brenda Gerhardt due to the restriction requirement.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "A host cell" encompasses a human organism. It is noted that "gene therapy" is contemplated, for example, on pages 5 & 17 of the specification. Therefore, it is suggested that amending the claims to "an isolated host cell" should obviate this particular rejection.

4. Claims 2-4 & 8-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Pages 1-2 of the specification disclose that "[t]he *novel* human proteins (NHPs) *described for the first time* herein share structural similarity with mammalian ion channel proteins, as well as a (*sic*) several proteins that have been designated as human secreted proteins..." [emphasis added] ". In contrast, not a single specific and assayable function is disclosed for the polynucleotide of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 5. For example, pages 16 & 21 of the specification disclose that "NHPs... can be used for the diagnosis of disease..., for screening for drugs... effective in the treatment of symptomatic or phenotypic manifestation of perturbing the normal function of a NHP in the body", as well as "for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and diseases". In contrast, not a single specific disease state that putatively can be treated by using these "novel human proteins (NHPs) described for the first time herein" is disclosed; especially as it relates to the encoded polypeptide of SEQ ID NO: 5. Moreover, because many polynucleotides may be useful "as hybridization probes for screening libraries" or for "RFLP analysis", and because many genes are putatively important in "diagnosis, drug screening, clinical trial monitoring, the treatment of diseases and disorders, and cosmetic or nutriceutical (*sic*) application" if some association with a specific "mental, biological, or medical disorder and disease", etc. was known in the art, no "specific" utility exists, because the specific biological activity for even the specific encoded NHP polypeptide depicted as SEQ ID NO: 5 is not known nor specifically described within the specification, and therefore, one cannot reasonably extrapolate what constitutes a specific utility for the polynucleotide of SEQ ID NO: 4.

Secondly, because no specific utility is described or known for the human NHP polynucleotide of SEQ ID NO: 4, and because the specification merely and generically states that NHP's may be useful for the "therapeutic treatment of mental, biological, or medical disorders and diseases", or may be useful for "the treatment of symptomatic or phenotypic manifestation of perturbing the normal function of a NHP in the body", etc., which are further unknown and not disclosed at the time of filing Applicants' invention, the instant invention also has no "substantial utility" because further experimentation is necessary at the time of filing the instant invention to attribute and discover a "real world" utility to the polynucleotide of SEQ ID NO: 4.

Applicants are directed toward the Utility Guidelines in MPEP 2107. See especially MPEP 2107.03.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 & 8-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
June 24, 2004
1600

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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